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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/511,989	05/25/2005	Jenny P Y Ting	5470-368	4540

20792 7590 01/24/2007  
MYERS BIGEL SIBLEY & SAJOVEC  
PO BOX 37428  
RALEIGH, NC 27627

EXAMINER
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PRIEBE, SCOTT DAVID

ART UNIT	PAPER NUMBER
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1633

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
31 DAYS	01/24/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

# Office Action Summary

Application No.

10/511,989

Applicant(s)

TING ET AL.

Examiner

Scott D. Priebe, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-54 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-54 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_.

### **DETAILED ACTION**

The information disclosure statement filed on 12/22/05 does not fully comply with the requirements of 37 CFR 1.98(d) because copies of most of the non-patent documents listed on the PTO-1449 have not received by the Office. Specifically, copies of the documents numbered 4-37 (AF389420 through NM\_170122), 46 (Beg et al.), 48-51 (second Bertin et al. through Brown et al.), 54-55 (Cressman et al. and Dangl et al.), 57-66 (Dode et al. through Harton et al.), 68-80 (Hemmi et al. through Kretsovali et al.), 83-94 (MacKeigan et al. through Poltorak et al.), 96 (Riley et al.), 98-106 (Schuster et al. through Stehlik et al.), and 108-122 (Suzuki et al. through Zhu et al.) have not been received. Failure to timely provide the missing copies will result in the above mentioned information disclosure statement being placed in the application file with the non-complying information **not** being considered. See 37 CFR 1.97(i).

### ***Election/Restrictions***

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1, 3, 4, 5-8, 16, 20, drawn to an isolated nucleic acid encoding a functional fragment of a Monarch-1 polypeptide.

Group II, claim(s) 1, 3, 4, 9, 16, 20, drawn to an isolated nucleic acid encoding a functional fragment of a CATERPILLER 11.2 polypeptide.

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Group III, claim(s) 1, 3, 4, 10, 11, 16, 20, drawn to an isolated nucleic acid encoding a functional fragment of a CATERPILLER 11.3 polypeptide.

Group IV, claim(s) 1, 3, 4, 12, 16, 20, drawn to an isolated nucleic acid encoding a functional fragment of a CATERPILLER 16.1 polypeptide.

Group V, claim(s) 1, 3, 4, 13, 16, 20, drawn to an isolated nucleic acid encoding a functional fragment of a CATERPILLER 16.2 polypeptide.

Group VI, claim(s) 1, 3, 4, 14-16, 20, drawn to an isolated nucleic acid encoding a functional fragment of a CIAS1 polypeptide lacking exon 4 and having exon 6.

Groups VII-XII, claim(s) 17-19, 21-23, 45-49, 53 (each in part), each group drawn to, in order, an isolated Monarch-1, CATERPILLER 11.2, CATERPILLER 11.3, CATERPILLER 16.1, CATERPILLER 16.2, and CIAS1 polypeptide, respectively, and the first recited method of using each in a cell-free method to identify compounds that bind to or modulate activity of each respective polypeptide.

Groups XIII-XVIII, claim(s) 24-27, 30, 31, 34, 35, 38, 39, 42-44 (each in part), each group drawn to an antibody that binds, in order, an isolated Monarch-1, CATERPILLER 11.2, CATERPILLER 11.3, CATERPILLER 16.1, CATERPILLER 16.2, and CIAS1 polypeptide, respectively, and the first recited method of using each respective antibody in a method for modulating cellular activity of Monarch-1, CATERPILLER 11.2, CATERPILLER 11.3, CATERPILLER 16.1, CATERPILLER 16.2, and CIAS1 polypeptide, respectively.

Groups XIX-XXIV, claim(s) 27, 28, 31, 32, 35, 36, 39, 40, 43, 44 (each in part), each group drawn to a method for modulating cellular activity of, in order, a Monarch-1, CATERPILLER 11.2, CATERPILLER 11.3, CATERPILLER 16.1, CATERPILLER 16.2, and CIAS1 polypeptide, respectively, by introducing a nucleic acid encoding the polypeptide.

Groups XXV-XXX, claim(s) 27, 29, 31, 33, 35, 37, 39, 41, 43, 44 (each in part), each group drawn to a method for modulating cellular activity of, in order, a Monarch-1, CATERPILLER 11.2, CATERPILLER 11.3, CATERPILLER 16.1, CATERPILLER 16.2, and CIAS1 polypeptide, respectively, by introducing an antisense oligonucleotide that targets the gene encoding the polypeptide.

Groups XXXI-XXXVI, claim(s) 27, 29, 31, 33, 35, 37, 39, 41, 43, 44 (each in part), each group drawn to a method for modulating cellular activity of, in order, a Monarch-1, CATERPILLER 11.2, CATERPILLER 11.3, CATERPILLER 16.1, CATERPILLER 16.2, and CIAS1 polypeptide, respectively, by introducing a siRNA that targets the gene encoding the polypeptide.

Groups XXXVII-XLII, claim(s) 45-52 (each in part), each group drawn to a cell-based method to identify compounds that bind to or modulate activity of, in order, a Monarch-1, CATERPILLER

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11.2, CATERPILLER 11.3, CATERPILLER 16.1, CATERPILLER 16.2, and CIAS1 polypeptide, respectively.

Groups XLIII-XLVIII, claim(s) 45-49, 53 (each in part), each group drawn to a method to identify compounds that bind to or modulate activity of, in order, a Monarch-1, CATERPILLER 11.2, CATERPILLER 11.3, CATERPILLER 16.1, CATERPILLER 16.2, and CIAS1 polypeptide, respectively, while being recombinantly expressed in a transgenic animal.

The inventions listed as Groups I-XLVIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The nucleic acid of Groups I-VI does not have a special technical feature, since nucleic acid encoding at least a functional fragment of each of the proteins were known. See for example US 2001/0029033 for Monarch-1; clone RP11-413N10 in GenBank Acc. No.AC090160, nucleotides 125661-149581, for CATERPILLER 11.2; GenBank Acc. No. AK025131 for CATERPILLER 11.3; GenBank Acc. Nos. AF389420 and AK025212 for CATERPILLER 16.1; cosmid 367E12 in GenBank Acc. No. AC004644 for CATERPILLER 16.2; and GenBank Acc. No. AF410477 for CIAP1 (comprises instant SEQ ID NO: 33). Since these groups do not have a special technical feature, they share none with the other groups. Furthermore, each of these proteins are structurally and functionally different, and thus share no technical feature with each other.

Unity of invention is lacking between different products or between multiple methods of using the same product, 37 CFR 1.475.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found

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XXX, XXXI-XXXVI, XXXVII-XLII, and XLIII-XLVIII do not use the isolated polypeptides or antibodies of groups VII-XII and XIII-XVIII, and thus unity of invention is lacking between these methods and products. The methods of groups XXV-XXX and XXXI-XXXVI, respectively, use structurally and functionally different compounds, antisense oligonucleotides and siRNA, respectively, and thus lack unity of invention. Groups XXXVII-XLII and groups XLIII-XLVIII, respectively, use different products, cells vs. transgenic animals, and their common technical feature is the nucleic acid of groups I-VI, respectively, which is not a special technical feature.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained.

Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder

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in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

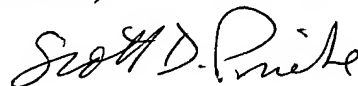
Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Scott D. Priebe, Ph.D. whose telephone number is (571) 272-0733. The examiner can normally be reached on M-F, 8:00-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach, Ph.D. can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Scott D. Priebe, Ph.D.  
Primary Examiner  
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